DEC 10 2010

Genesys Spine Interbody Fusion System

Premarket Notification

SUBMITTED BY	Genesys Spine 1250 Capital of Texas Highway South Building Three, Suite 600 Austin, TX 78746
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	Pending
CONTACT PERSON	Josh Kaufmann Principal Genesys Spine Phone: 512-560-3446 Fax: 800-817-4938
SUBMISSION PREPARED BY	Lisa Peterson QA Consulting, Inc. Phone: 512-507-0746
DATE PREPARED	October 11, 2010
CLASSIFICATION NAME	Intervertebral Fusion Device with Bone Graft, Lumbar Intervertebral Fusion Device with Bone Graft, Cervical Spinal Intervertebral Body Fixation Orthosis
DEVICE CLASS	Class II
REGULATION NUMBER	888.3080 (Product Code: MAX) 888.3080 (Product Code: ODP) 888.3060 (Product Code: MQP)
COMMON NAME	Intervertebral Body Fusion Device (MAX, ODP) Spinal Vertebral Body Replacement Device (MQP)
PROPRIETARY NAME	Genesys Spine Interbody Fusion System
IDENTIFICATION OF PREDICATE DEVICE(S)	Predicate devices include various cleared interbody fusion and VBR systems: - RAY® Threaded Fusion Cage (P950019) - Lumbar I/F Cage (P960025) - InterFix (P970015) - BAK/C (P980048) - Affinity Cage System (P000028) - MC+ (K043479, K091088) - Eminent Spine System (K090064)

DEVICE DESCRIPTION

The Genesys Spine Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:

1) Genesys Spine cervical interbody fusion device(s), which may be implanted as a single device via an anterior approach.

2) Genesys Spine lumbar interbody fusion device(s), which may be implanted
   - bi-laterally via a posterior (PLIF) approach;
   - as a single device via a transforaminal (TLIF) approach; or
   - as as a single device via an anterior/anterolateral (ALIF) approach.

3) Genesys Spine vertebral body replacement device(s), which may be implanted in the thoracic and/or thoracolumbar spine (T1-L5).

The Genesys Spine Interbody Fusion System implant components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The Genesys Spine Interbody Fusion System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel materials that conform to ASTM F899.

INDICATIONS

When used as a cervical intervertebral body fusion device, the Genesys Spine Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

When used as a lumbar intervertebral body fusion device, the Genesys Spine Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

When used as a vertebral body replacement device, the Genesys Spine System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The device system is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device system is intended to be used with autograft or allograft bone.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The purpose of this premarket notification is to obtain clearance to market the Genesys Spine Interbody Fusion System. The Genesys Spine Interbody Fusion System is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The Genesys Spine Interbody Fusion System implant components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The subject system has similar technological characteristics as the predicate devices identified above. Specifically, the following characteristics support this conclusion:

- Intended for use at one level from the C2-C3 disc to the C7-TI disc for the treatment degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at the involved level.
- Intended for use at either one level or two contiguous levels from L2-S1 for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
- When used as a VBR, the implants are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column (T1-L5) even in the absence of fusion for a prolonged period.
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-03), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02)

DISCUSSION OF NON-CLINICAL TESTING

The following non-clinical tests were conducted:

- Static and dynamic compression testing, conducted in accordance with ASTM F2077-03
- Static and dynamic torsion testing, conducted in accordance with ASTM F2077-03
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

CONCLUSIONS

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Genesys Spine Interbody Fusion System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Genesys Spine
% Mr. Josh Kaufmann
1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

DEC 10 2010

Re: K103034
Trade/Device Name: Genesys Spine Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP
Dated: October 11, 2010
Received: October 13, 2010

Dear Mr. Kaufmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **Genesys Spine Interbody Fusion System**

Indications for Use:

When used as a cervical intervertebral body fusion device, the Genesys Spine Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

When used as a lumbar intervertebral body fusion device, the Genesys Spine Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

When used as a vertebral body replacement device, the Genesys Spine System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The device system is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device system is intended to be used with autograft or allograft bone.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103034

Genesys Spine

1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

Phone: 512-560-3446
Fax: 800-817-4938